5. 510(k) Summary

K011826

JAN 2 4 2002

5.1 21 CFR 807.92(a)(1) - Submitter details

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Date the summary was prepared:	25th May 2001

5.2 21 CFR 807.92(a)(2) - Device name

Trade name:	Micropace model EPS320 Clinical Stimulator
Common name:	Programmable Cardiac Electrophysiological Stimulator
Classification name:	External programmable pacemaker pulse generator (Per 21 CFR section 870.1750)

5.3 21 CFR 807.92 (a)(3) - Identification of Substantially Equivalent device

Predicate Company name	Predicate Device name
Digital Cardiovascular Instruments Inc. Berkeley CA	DCI Model EP-2 Clinical Stimulator

5.4 21 CFR 807.92 (a)(4) - Description of the Micropace model EPS320

The Micropace EPS320 Cardiac Stimulator (Clinical Stimulator) is an external programmable computerised diagnostic cardiac stimulator. It is used in specialised hospital electrophysiological diagnostic laboratories by specialist cardiologists to electrically stimulate the heart to initiate and terminate tachyarrhythmias and allow measurement of refractory and conduction properties of the heart by third party equipment.

The EPS320 system consists of a Stimulus Generator Unit (**SGU**) comprising of a manufactured metal instrument case 12.25"(W) x 13.25"(D) x 3.5"(H) and a standard IBM clone type Personal Computer (**PC**), the two interconnected by a serial data connection. The device has two independent fully programmable and isolated constant current pulse generator channels intended for temporary stimulation of the heart via third party transvenous intracardiac electrodes. The pacing stimulus is output via a Stimulus Connection Box and may typically be routed to the intravenous pacing electrodes via third party electronic switching equipment.

During normal operation of the EPS320, custom software on the PC provides keyboard input device and a graphical user interface which the operator uses to control the stimulation process in real time. The custom PC software interprets the user instructions and sends specific real-time commands to the SGU via the serial (RS232) data link to control its function and generate appropriate pacing stimulus pulses. The two isolated outputs can deliver stimulus pulse widths from 0.5ms to 10ms, adjustable in 0.5 to 1ms steps with current amplitudes adjustable from 0.1mA to 25mA in steps of 0.1mA. Current delivery is limited within the specified range by a maximum available output voltage of 26V.

The EPS320 is not a life support device and may be used only in the presence of a backup cardiac pulse generator. In case of failure of mains power supply, malfunction of the PC or its software, or loss of the data link, the SGU can operate independently of the PC in the Manual Backup mode, powered by an internal backup battery. This operational mode can provides regular pacing stimuli at intervals and pulse current amplitudes programmable from and displayed on the SGU's front panel. It may be used to briefly support a bradycardic patient until temporary external pacing is established using an approved temporary pacemaker. A secondary electrically self-contained Emergency Fixed Pace Output port on the front of the SGU may be used for the same purpose in case of loss of normal SGU function.

The EPS320 is an expert-designed product, based upon the electrophysiological expertise of the cardiologist Managing Director and on extensive post market experience with an earlier EPS220 model in service in eight (8) Australian hospitals since 1995. The current and earlier EPS320 models have been in clinical use in more than 40 clinical centres predominantly in Australia, Europe and India, as well as in Turkey, Vietnam and China for up to 4 years without significant adverse effects.

5.5 21 CFR 807.92 (a)(5) – Statement of the Intended Use

INTENDED USE:

The EP320 stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

5.6 21 CFR 807.92 (a)(6) - Summary of Technological differences

This section compares the specifications and other relevant performance characteristics of the EPS320 and the predicate device, EP-2. It tabulates the compared items side by side and then specifies the rationale for claims of substantial equivalence.

5.6.1 Definition of terms used in the following tables

TERM	DEFINITION	TERM	DEFINITION
ISI	Interstimulus Interval	SNRT	Sinus Node Recovery Time
ERP	Effective Refractory Period	ATP	Anti Tachycardia Pacing
PC	Personal Computer	SGU	Stimulus Generator Unit
ECG	Electrocardiograph	IEC	International Electrotechnical Commission
IECG	Intracardiac ECG	AICD	Automatic Implantable Cardioverter Defibrillator

5.6.2 Technological differences between devices.

A comparison of published performance specifications in the "Specifications" sections of the EPS320 and in the equivalent section of the predicate device, EP-2 documentation is shown in Table 5-1 below.

Comparative element	DCI Model EP – 2 (Predicate Device)	Micropace model EPS320
A. Manufacturer	Digital Cardiovascular Instruments, Inc. Berkeley, CA	Micropace Pty Ltd. Campsie, N.S.W Australia
B. FDA Concurrence	Yes (K854196/B)	Pending
1. Isolated Stimulus Channels	2	2
2. Pulse Amplitude –		
Range	0.1-20 mA (2500 Ω load)	0.1 to 25mA into 800 Ω load
Increment		0.1 mA up to 1mA Amplitude
Accuracy	5% or 0.2 mA (whichever is larger)	± 2% or ± 0.2 mA, (whichever is greater)
3. Pulse duration		
Range	0.5-10 msec (maximum 10% of ISI)	0.5 to 10 msec
Increment	0.1 msec	0.5 – 10msec, increments of 1 – 10 msec
Accuracy	0.05 msec (Pulse amplitude > 2 mA)	± 0.15ms
4. Interstimulus Interval (ISI)		
Range	100-10000 ± 1 msec	180 msec to 9990 msec ± 1msec or 0.1% (whichever is greater)

Comparative element	DCI Model EP – 2 (Predicate Device)	Micropace model EPS320
Range (Burst)	10-1000 ± 1 msec	30 - 9900 msec ± 1msec or 0.1% (whichever is greater)
Increment	1 msec	1 msec
5. Sequential (AV) Delay		
Range	10-1000 ± 1 msec (maximum ISI – 50 msec)	Min: 25 - 980msec (maximum ISI – 120 msec)
Increment	1 msec	1 msec
6. Reprogrammed Protocols	Threshold Refractory study Wenckebach block SA Node recovery Pace Burst Overdrive Underdrive Arrhythmia Induction Refractory Threshold	Threshold, Nodal ERP / RSync_S2 Wenckebach SNRT Pace Burst Pace Overdrive Burst / Load ATP - Multi-Sx -
7. Programmable Protocol keys	5	5 programmable stimulator complete set-ups
8. Number of Extrastimuli	6 (s2-s7)	Max: 6 (s2-s7)
9. Sensing (ECG synchronisation)		
Automatic or manual trigger setting – Sensitivity	1-500 mV	External: 50 – 2000mV Internal: Pacing catheter tip
Automatic or manual trigger setting – Trigger lockout (refractory time)	10-1000 msec (100 Hz max)	50 – 5000msec
Automatic or manual trigger setting – ECG delay	100-5000 msec	50-5000msec
10. Additional Outputs:	Stimulus Channel A Marker	Sync 3 Input Marker
	Stimulus Channel B Marker	Sync 3 Input Marker
	Programmable Auxiliary/Paper advance	Sync 1 Input Marker Sync 2 Input Marker
	ECG trigger marker	N/A
11. Power Source	Internal rechargeable 6V battery	Main power source: 2201-240VAC or 110-120VAC to 14.5 VDC, 750mA Low Voltage Power Supply Transformer Backup power: 1. 12V 2.1Ah lead acid battery Backup power: 2. 9V PP3 Lithium battery
Battery operating time:	17 hours (typical)	Indefinite (Mains operated)
12. Stimulation Module		
Physical Dimensions (inches)	3.0 x 12.0 x 14.0	3.3 x 12.25 x 13.25

1 Input electrical mains voltage will be dependant on geographical location/available mains voltage

Comparative element	DCI Model EP – 2 (Predicate Device)	Micropace model EPS320
Weight (lbs)	11.2	18. 7
13. Control Terminal		
Listings	UL	UL & CE
Type	14 in diagonal green phosphor CRT	PC with LCD display
Display dimensions (inches)	13.5 x 14 x 15	12 wide x 9 high x 3 deep (flat Screen)
Footprint dimensions (inches)	12.25 x 10.25	10.6wide x 7.5deep x 15high (including LCD panel)
Keyboard dimensions (inches)	2.25 x 17.25 x 7.6 Modified QWERTY keyboard	1.6 high x 19.0 wide x 8.4 deep Modified QWERTY keyboard
Weight (lbs)	31.5	Approx. 12.0 lb.
14. Isolation Transformer		
Leakage current	Less than 100 μA	Less than 100 μA
Power rating	500 VA	400VA
Physical dimensions (inches)	8.12 x 9.00 x 6.75	7.75 x 5 x 4
Weight (lbs)	22	15.4
15. Charger		
Listings	UL544 3-prong wall plug-in, automatic cut-off	Internal SGU 'on-board' circuitry
Charge/Discharge time ration	Less than 1	Less than 1
Charge time from low battery indication to full charge	< 16 hours	<16 hours
Dimensions (inches)	2.55 x 2.89 x 1.88	N/A
16. Environment		
Operating Temperature	+10 to +40 degrees Celsius	+10 to +40 degrees Celsius
Storage Temperature	-20 to +60 degrees Celsius	-20 to +60 degrees Celsius
Relative Humidity	25% to 90% non-condensing	25% to 90% non-condensing
Operating Altitude	0 to 4572 m	0 to 4572 m
Storage Altitude	0 to 7620 m	0 to 7620 m

Table 5-1 Substantial Equivalence Comparison -1

Table 5-2 below lists technological differences in performance characteristics between the EPS320 and the predicate EP-2 device not included in the "Specifications" section of either device.

Comparative item	DCI Model EP – 2 (Predicate Device)	Micropace model EPS320
1. Hardware computer platform	"Control Terminal" custom computer / custom "Stimulus Module"	Standard "PC" Personal Computer / custom "Stimulus Generator Unit "
2. User interface		
Output	Text Windowed Display	Graphical Windowed Display
3. ECG Sensing		
Catheter-Tip IECG sensing	No	Yes
Balanced Charge Pacing	No	Yes

4. Device feedback to user		
Open Pacing Circuit Warning	No	Yes
Stimulation impedance display	No	Yes
Graphical display of ECG Trigger	No	Yes
5. Backup Pacing Circuits	No	Yes (2)
6. Stimulation Protocol Implementation		
A-V Joined Pacing Stimulation	Limited	Yes
Load_ATP - AICD-Style Overdrive Pacing	No	Yes
ECG trigger time out	No	Yes
On the fly programming of all parameters	Limited	Yes
Shortcut Keys	Yes	Yes (different)

Table 5-2 Substantial Equivalence Comparison -2

5.6.3 Rationale for claims of equivalence of devices

The EPS320 and the predicate device are equivalent in their published specifications (see Table 5-1) for the following reasons:

Table 5.1 Section	Reduced safety or effectiveness issues?	Is the EPS320 as safe and effective as the EP-2? (Rationale)
1 Isolated Stimulus Channels	No	Same number of Channels as the EP-2.
2 Pulse Amplitude	No	EPS320 output current is sufficient for therapeutic purposes and substantially the same as the EP-2.
3 Pulse duration	No	Pulse Duration is within the profession's accepted requirements as attested by 4 years of post-market surveillance of the EPS320.
4 Interstimulus Interval (ISI)	No	Substantially the same as the EP-2.
5 Sequential (AV) Delay	No	A-V delay is substantially the same as the EP-2. EPS320 is limited to ISI less 120 msec which is considered an enhanced safety feature whilst retaining equivalent operational effectiveness.
6 Reprogrammed Protocols	No	EPS320 contains an equivalent protocol to all but 1 protocol in the EP-2, providing substantially equivalent functionality. One protocol, the Refractory Threshold protocol present in the EP-2 is no longer in common clinical use in the experience of the expert designer and was not included in the EPS320.

Table 5.1 Section	Reduced safety or effectiveness issues?	Is the EPS320 as safe and effective as the EP-2? (Rationale)
7 Programmable Protocol keys	No	EPS320 implements programmability by storing and recalling complete stimulator set ups rather than individual dual protocols. The two approaches are basically functionally similar.
8 Number of Extrastimuli	No	The number of selectable extra stimuli is the same as the EP-2, dependant on the protocol selected.
9 Sensing (ECG synchronisation	No	External ECG input range (mV) for the EPS320 is appropriate for common external ECG sources found in contemporary laboratories. Presence of pacing catheter tip sensing in EPS320 is considered an enhanced safety feature in providing an additional source of ECG trigger. Longer minimum lockout in EPS320 (50 vs. 10msec) is an enhanced safety feature reducing susceptibility to noise, without significant loss of functionality. Lockout period and ECG delay are substantially equivalent to the EP-2
10 Additional Outputs:	No	Sync 3 output on the EPS320 provides essentially the same function as Stimulus Ch 'A' and Stimulus Ch 'B' outputs of the EPS320 There is no requirement for an auxiliary (printer) output on the EPS320 as it is connected to recording external systems.
11 Power Source	No	All components of the EPS320 system are powered from electrical mains power via an isolation transformer. The SGU is powered from this isolated mains by a 14.5V DC Power Supply Unit containing a transformer. The EPS320 system, including these accessories (isolation transformer and DC Power Supply Unit, have been subjected to appropriate electrical and safety tests (See appendix A1 and A2). Mains source of power was considered safer than a battery as it removes the possibility of lack of device availability due to depleted batteries. Batteries contained in the EPS320 are used solely under fault conditions.
12 Stimulation Module	No	Physical attributes of the EPS320 are substantially the same as the EP-2, whilst maintaining operational functionality in similar environment
13 Control Terminal	Yes	The Computer used with the EPS320 can have software files added by the operator creating potential for corruption of operating environment. To control this possibility, the EPS320 software checks for integrity of operating environment during startup. Other parameters are essentially equivalent as the EP-2 terminal.
14 Isolation Transformer	No	The Isolation transformer is essentially equivalent to that described in the EP-2 documentation.
15 Charger	No	The EPS320 does not require a separate battery charger. Batteries are not required for normal operation.
16 Environment	No	Environmental conditions are essentially equivalent as the EP-2.

Table 5-3 Rationale of the data in Table 5-1

The EPS320 and the predicate device are equivalent in performance characteristics other than specifications (see Table 5-2) for the following reasons:

Table 5.2 Section	Reduced safety or effectiveness issues?	Is the EPS320 as safe and effective as the EP-2? (Rationale)
1. Hardware platform	Yes	Both devices have similar architectures, in that a microprocessor is used to control output pulse generation circuitry, and a physically separate computing device is used to provide user interface via a video display unit and a keyboard. The two devices differ predominantly in using different implementations to achieve similar functional requirements. The EP-2 used propriety microprocessor software whereas the EPS320 uses an 'open PC architecture' – a standard PC loaded with custom software. There will also be differences in software architectures and interface designs and implementations. The EPS320 system removes the danger of corruption of software environment from unauthorised addition of third party software or incorrect operating systems by verification of software environment and resource integrity prior to startup. The custom software is implemented on a stable DOS platform and its design is based on extensive risk analysis and subject to appropriate design control, verification and validation. The absolute safety and efficacy of the EPS320 hardware platform has been demonstrated in clinical practice and is thus at least equivalent to that of the predicate EP-2 device.
2. User interface	No	The user interface **displays** and input **keyboards** of the two devices are substantially functionally equivalent technologies. Software performance of the EPS320 is designed for user flexibility and ergonomy and while these performance features probably represent the main functional difference between the EPS320 and the predicate device they have limited impact on device safety.
3. ECG Sensing	No	**Catheter-Tip IECG sensing**: The predicate EP-2 can trigger only on an external ECG source, which is usually derived from third party equipment which amplifies the patient's intracardiac ECG (IECG) or surface ECG. The EPS320 contains an ECG amplifier connected to the pacing channel and can thus trigger on this IECG source or on an external ECG source. **Balanced Charge Pacing**: This feature refers to a configuration of IECG amplifier sensing between stimulation pulses to minimise electrical charge build up on the pacing electrodes. It has no impact on the stimulation pulse shape, amplitude or efficacy and thus has no performance or safety impact.

4. Device feedback to user	No	**Open Pacing Circuit Warning:** This feature indicates to the user when programmed stimulation current fails to be delivered to the patient. **Stimulation impedance display:** This feature displays to the user approximate stimulus-to-stimulus impedance of the stimulation circuit. **Graphical display of ECG Trigger:** This feature conveys to the user the quality of the ECG source used for Triggering. These features are safety enhancements over the predicate device EP-2.
5. Backup Pacing Circuits	No	The EPS320 has a **Manual Backup** operation mode which operates in the absence of a correctly functioning computer and allows user to perform simple stimulation tasks. The EPS320 also contains a separate, self-powered **Emergency Fixed Pace** circuit, capable of delivering pacing stimuli in the case of loss of function of the Stimulus Generator Unit. These functions are safety enhancements over the predicate device EP-2.
6. Stimulation Protocol Options	No	Both devices provide predominantly equivalent stimulation protocols with differences confined to issues hotkey and menu layout, ergonomy and user convenience. Below are representative examples. **A-V Joined Pacing Stimulation:** This stimulation allows simultaneous stimulation of both output channels for only some pacing stimuli in a pacing protocol and not others. **Load_ATP – AICD-Style Overdrive Pacing:** This additional protocol in the EPS320 is an automated combination of the Burst and Overdrive protocols in the predicate device. **ECG trigger time out:** In case of failure of arrival of a Trigger event, pacing will commence in any case after this period of time. **On the fly programming of all parameters:** All pacing parameters can be altered by hotkeys without stopping stimulation. **Shortcut Keys:** Various shortcut keys, different to the predicate device, are implemented to enhance efficiency of use.

Table 5-4 Rationale of the data in Table 5-2

5.6.4 Conclusion

The discussion above demonstrates that the EPS320 and the predicate device EP-2 posses similar architectural and functional characteristics, although differences exist in the specific technological implementation of some of the functional requirements. The EPS320, has demonstrably greater number of safety characteristics than the EP-2.

5.7 21 CFR 807.92 (b)(2) - Clinical comparison to the predicate device

Not Applicable

5.8 21 CFR 807.92 (b)(3) - Clinical & non-clinical test conclusions

Having analysed the characteristics that differ and those which are similar between the Model EP-2 and Model EPS320, we have concluded that, in our opinion:

- The intended use of the EPS320 and EP-2 are the same.
- Safety of the EPS320 is as effective if not more effective than the predicate device.
- Differences between the systems are limited to the technological implementation of equivalent functions, layout design and ergonomy of the user interface
- The EPS320 is substantially equivalent to the EP-2 .

5.9 21 CFR 807.92 (c) – 510(k) Summary

Presentation of the 510[k] summary is considered compliant with the requirements of this section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2002

Mr. Michael Cejnar
Micropace Pty. Ltd.
571 Canterbury Road
Campsie, NSW 2194 Australia

Re: K011826
EPS320 Cardiac Stimulator
Regulation Number: 870.1750
Regulation Name: External Programmable Pacemaker Pulse Generator
Regulatory Class: Class II (two)
Product Code: JOQ
Dated: October 23, 2001
Received: October 26, 2001

Dear Mr. Cejnar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. In addition, if you wish to change or expand the current indications for use to include non-military environments, you will need to submit a new 510(k) premarket notification, and receive FDA clearance prior to marketing the device.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Statement of Indications for Use

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Micropace Pty Ltd.

510(k) Number (if known): K011826

Device Name: EPS320

Indications For Use:

The EPS320 Stimulator System is an electrical stimulus generator for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011826